

IN THE UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
TAMPA DIVISION

JULIA W. ROSE,

Plaintiff,

vs.

CASE NO.: 8:07-cv-01825-JDW-EAJ

PFIZER INC.;  
PHARMACIA CORPORATION, a wholly-  
owned subsidiary of PFIZER INC.;  
PHARMACIA & UPJOHN COMPANY,  
LLC, a wholly-owned subsidiary of  
PHARMACIA CORPORATION,

Defendants.

**DEFENDANTS PFIZER INC., PHARMACIA CORPORATION,  
AND PHARMACIA & UPJOHN COMPANY LLC'S  
ANSWER AND DEFENSES AND JURY DEMAND**

NOW COME Defendants Pfizer Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and Pharmacia & Upjohn Company LLC (improperly captioned in Plaintiff's Complaint as "Pharmacia & Upjohn Company, LLC") ("Pharmacia & Upjohn") (collectively "Defendants"), and file this Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

**I.  
PRELIMINARY STATEMENT**

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Bextra®.

**II.**  
**ANSWER**

1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but deny that Plaintiff is entitled to any relief or damages. Defendants deny the remaining allegations in this paragraph of the Complaint.

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Pfizer is registered to do and does business in the State of Florida. Defendants deny the remaining allegations in this paragraph of the Complaint.

6. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants deny the remaining allegations in this paragraph of the Complaint.

7. Defendants admit that, as the result of a merger in April 2003, Pharmacia became a subsidiary of Pfizer. Defendants deny the remaining allegations in this paragraph of the

Complaint.

8. Defendants deny that Pharmacia & Upjohn Company LLC ever designed, produced, manufactured, marketed, sold, resold, or distributed Bextra®, and deny that it is a proper party in this suit. Defendants deny the remaining allegations in this paragraph of the Complaint. The response to this paragraph of the Complaint regarding Pharmacia & Upjohn is incorporated by reference in response to each and every paragraph of the Complaint referring to Pharmacia & Upjohn and/or Defendants.

9. Defendants deny that Defendant Pharmacia & Upjohn Company LLC ever designed, produced, manufactured, marketed, sold, resold, or distributed Bextra®, and deny that it is a proper party in this suit. Defendants deny the remaining allegations in this paragraph of the Complaint.

10. Defendants deny that Defendant Pharmacia & Upjohn Company LLC ever designed, produced, manufactured, marketed, sold, resold, or distributed Bextra®, and deny that it is a proper party in this suit. Defendants deny the remaining allegations in this paragraph of the Complaint.

11. The allegations in this paragraph of the Complaint assert legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny that Defendant Pharmacia & Upjohn Company LLC ever designed, produced, manufactured, marketed, sold, resold, or distributed Bextra®, and deny that it is a proper party in this suit. Defendants deny the remaining allegations in this paragraph of the Complaint.

12. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States, including Florida, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of

the Complaint.

13. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

15. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs (“NSAIDS”). Defendants state that, as stated in the FDA-approved labeling for Bextra®, “[t]he mechanism of action is believed to be due to inhibition of prostaglandin synthesis primarily through inhibition of cyclooxygenase-2 (COX-2). Defendants deny the remaining allegations in this paragraph of the Complaint.

16. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs (“NSAIDS”). Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

17. The allegations in this paragraph of the Complaint are not directed toward

Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

18. The allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

19. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

20. Defendants admit that Bextra® was approved by the FDA on November 16, 2001. Defendants state that, as stated in the FDA-approved labeling for Bextra®, “[t]he mechanism of action is believed to be due to inhibition of prostaglandin synthesis primarily through inhibition of cyclooxygenase-2 (COX-2). Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Plaintiff does not allege having used Celebrex® in this Complaint. Nevertheless, Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to

prescribe drugs in accordance with their approval by the FDA. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny the remaining allegations in this paragraph of the Complaint.

21. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

22. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

23. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants state that Bextra® was and is safe and effective when used in

accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

24. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

25. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

26. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

27. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved

prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

28. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

29. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

30. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

31. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the



potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

32. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

33. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

34. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

35. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved

prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

36. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

37. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

38. Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

39. Defendants state that Bextra® was and is safe and effective when used in

accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

40. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

41. Defendants admit that the FDA Division of Drug Marketing, Advertising, and Communications (“DDMAC”) sent a letter to Pfizer dated January 10, 2005. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

42. Defendants state that the referenced FDA Public Health Advisory speaks for itself and respectfully refer the Court to the Public Health Advisory for its actual language and text. Any attempt to characterize the Public Health Advisory is denied. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market as of April 7, 2005. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and

deny the remaining allegations contained in this paragraph of the Complaint, including all subparts.

43. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

44. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

45. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

46. Defendants state that Bextra® was and is safe and effective when used in

accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

47. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

48. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

49. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

50. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit that Bextra® was expected to reach consumers without substantial change from the time of sale. Defendants deny the remaining allegations this paragraph of the Complaint.

51. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

52. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to First Cause of Action: Strict Liability**

Answering the unnumbered paragraph following Paragraph 52 of the Complaint, Defendants state that the allegations in this paragraph of the Complaint assert legal contentions to which no response is required. To the extent that a response is deemed required, Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein. Defendants deny the remaining allegations in this paragraph of the Complaint.

53. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported

with applicable standards of care and law. Defendants admit that Bextra® was expected to reach consumers without substantial change from the time of sale. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

54. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

55. Defendants state that the allegations in this paragraph of the Complaint assert legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

56. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct deny the remaining allegations in this paragraph of the Complaint.

57. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the

potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct deny the remaining allegations in this paragraph of the Complaint.

58. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct deny the remaining allegations in this paragraph of the Complaint.

59. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

60. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining



allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 60 of the Complaint, Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Second Cause of Action: Negligence**

Answering the second unnumbered paragraph following Paragraph 60 of the Complaint, Defendants state that the allegations in this paragraph of the Complaint assert legal conclusions to which no response is required. To the extent that a response is deemed required, Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein. Defendants deny the remaining allegations in this paragraph of the Complaint.

61. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants deny the remaining allegations in this paragraph of the Complaint.

62. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

63. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the

potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

64. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 64 of the Complaint, Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Third Cause of Action: Negligent Misrepresentation**

Answering the second unnumbered paragraph following Paragraph 64 of the Complaint, Defendants state that the allegations in this paragraph of the Complaint assert legal conclusions to which no response is required. To the extent that a response is deemed required, Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein. Defendants deny the remaining allegations in this paragraph of the Complaint.

65. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

66. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff

used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

67. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

68. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

69. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny

that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

70. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

71. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

72. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

73. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

74. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

75. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

76. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 76 of the Complaint, Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Fourth Cause of Action: Fraud**

Answering the second unnumbered paragraph following Paragraph 76 of the Complaint, Defendants state that the allegations in this paragraph of the Complaint assert legal conclusions to which no response is required. To the extent that a response is deemed required, Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein. Defendants deny the remaining allegations in this paragraph of the Complaint.

77. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining

allegations in this paragraph of the Complaint.

78. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

79. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

80. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

81. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

82. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the

Complaint, including all subparts.

83. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

84. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

85. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

86. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct deny the remaining allegations in this paragraph of the Complaint.

87. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved

prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct deny the remaining allegations in this paragraph of the Complaint.

88. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

89. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following paragraph 89 of the Complaint, Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

### **III.**

#### **GENERAL DENIAL**

Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

### **IV.**

#### **AFFIRMATIVE DEFENSES**

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:



**First Defense**

1. The Complaint fails to state a claim upon which relief can be granted.

**Second Defense**

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

**Third Defense**

3. At all relevant times, Defendants provided proper warnings, information, and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

**Fourth Defense**

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed, and distributed.

**Fifth Defense**

5. Plaintiff's claims should be diminished in whole or in part in the amount paid to Plaintiff by any party or non-party with whom Plaintiff has settled or may settle.

**Sixth Defense**

6. Plaintiff's action is time-barred as it is filed outside of the time permitted by the

applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

**Seventh Defense**

7. Plaintiff's action is barred by the statute of repose.

**Eighth Defense**

8. Plaintiff's claims against Defendants are barred to the extent Plaintiff was contributorily negligent, actively negligent or otherwise failed to mitigate Plaintiff's damages, and any recovery by Plaintiff should be diminished accordingly.

**Ninth Defense**

9. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

**Tenth Defense**

10. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

**Eleventh Defense**

11. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

**Twelfth Defense**

12. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

**Thirteenth Defense**

13. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

**Fourteenth Defense**

14. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

**Fifteenth Defense**

15. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

**Sixteenth Defense**

16. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

**Seventeenth Defense**

17. Plaintiff’s alleged injuries/damages, if any, were the result of misuse or abnormal use

of the product Bextra® after the product left the control of Defendants and any liability of Defendants is therefore barred.

**Eighteenth Defense**

18. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

**Nineteenth Defense**

19. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

**Twentieth Defense**

20. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

**Twenty-first Defense**

21. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

**Twenty-second Defense**

22. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**Twenty-third Defense**

23. The manufacture, distribution, and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes,

and Plaintiff's causes of action are preempted.

**Twenty-fourth Defense**

24. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

**Twenty-fifth Defense**

25. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

**Twenty-sixth Defense**

26. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

**Twenty-seventh Defense**

27. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

**Twenty-eighth Defense**

28. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

**Twenty-ninth Defense**

29. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

**Thirtieth Defense**

30. Plaintiff's fraud and misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and/or Florida Rule of Civil Procedure 1.120 and should be dismissed.

**Thirty-first Defense**

31. Plaintiff's claims are barred because Bextra® was designed, manufactured, and marketed in accordance with the state of the art at the time of manufacture per section 768.1257, Florida Statutes.

**Thirty-second Defense**

32. Bextra® is not defective or unreasonably dangerous, and Defendants are not liable because, at the time of sale or distribution of the Bextra® alleged to have been used by Plaintiff, Defendants had complied with applicable regulations of the federal Food & Drug Administration and are entitled to application of section 768.1256, Florida Statutes.

**Thirty-third Defense**

33. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

**Thirty-fourth Defense**

34. Plaintiff failed to provide Defendants with timely notice of any alleged

nonconformance to any express representation.

**Thirty-fifth Defense**

35. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

**Thirty-sixth Defense**

36. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

**Thirty-seventh Defense**

37. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

**Thirty-eighth Defense**

38. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured, and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

**Thirty-ninth Defense**

39. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon

information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

**Fortieth Defense**

40. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

**Forty-first Defense**

41. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

**Forty-second Defense**

42. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

**Forty-third Defense**

43. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

**Forty-fourth Defense**

44. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.



**Forty-fifth Defense**

45. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

**Forty-sixth Defense**

46. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product's labeling contained the information that Plaintiff contends should have been provided.

**Forty-seventh Defense**

47. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

**Forty-eighth Defense**

48. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

**Forty-ninth Defense**

49. Plaintiff's injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiff, or persons or parties whose identities are unknown at this time, and such comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiff's recovery. Thus, Defendants are entitled to have their liability to the Plaintiff, if any, reduced as a result of the negligence or fault of said persons or entities, pursuant to the provisions of

section 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant to sections 768.31 and 768.81, Florida Statutes, judgment must be entered on the basis of Defendants' percentage of fault, taking into account the percentage of fault attributable to all other persons, whether or not a party hereto, and not on the basis of joint and several liability. The persons or entities referred to in this paragraph that are presently unknown to Defendants will be identified in a timely manner consistent with Nash v. Wells Fargo, 678 So. 2d 1262 (Fla. 1996).

#### **Fiftieth Defense**

50. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

#### **Fifty-first Defense**

51. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

**Fifty-second Defense**

52. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

**Fifty-third Defense**

53. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

**V.**  
**JURY DEMAND**

Defendants hereby demand a trial by jury.

**VI.**  
**PRAYER**

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiff take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's injuries and damages; and

6. That Defendants have such other and further relief as the Court deems appropriate.

s/ Edward W. Gerecke  
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Edward W. Gerecke  
Florida Bar No. 328332  
CARLTON FIELDS, P.A.  
Corporate Center Three at International Plaza  
4221 W. Boy Scout Blvd., Suite 1000 (33607)  
Post Office Box 3239  
Tampa, Florida 33601  
Telephone: (813) 223-7000  
Facsimile: (813) 229-4133  
E-Mail: [egerecke@carltonfields.com](mailto:egerecke@carltonfields.com)

Attorneys for Defendants Pfizer Inc., Pharmacia  
Corporation, and Pharmacia & Upjohn  
Company LLC

**CERTIFICATE OF SERVICE**

I CERTIFY that on the 15th day of October, 2007, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to C. Todd Alley, [talley@alleyingram.com](mailto:talley@alleyingram.com); James D. Clark, [jclark@tampatriallawyers.com](mailto:jclark@tampatriallawyers.com); Donald Greiwe, [dgreiwe@tampatriallawyers.com](mailto:dgreiwe@tampatriallawyers.com); and Brenda S. Fulmer, [bfulmer@tampatriallawyers.com](mailto:bfulmer@tampatriallawyers.com).

s/ Edward W. Gerecke  
\_\_\_\_\_  
Attorney